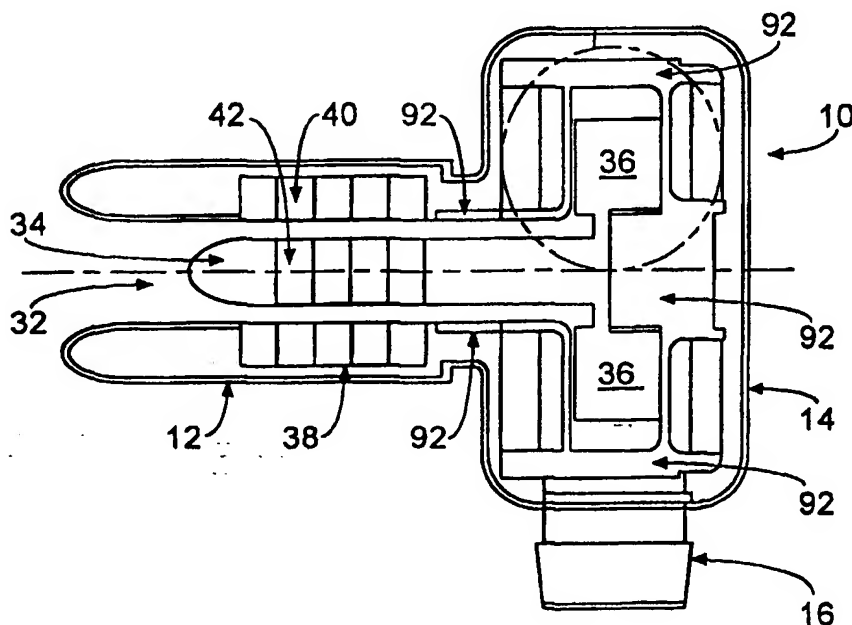


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61M 1/10, F04D 29/04	A1	(11) International Publication Number: WO 00/64508 (43) International Publication Date: 2 November 2000 (02.11.00)
(21) International Application Number: PCT/US00/09009 (22) International Filing Date: 6 April 2000 (06.04.00) (30) Priority Data: 09/301,138 28 April 1999 (28.04.99) US (71) Applicant (for all designated States except US): KRITON MEDICAL, INC. [US/US]; 6790 Florin-Perkins Road, Sacramento, CA 95828-1812 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): WAMPLER, Richard, K. [US/US]; 7827 Prospect Court, Granite Bay, CA 95746 (US). LANCISI, David, M. [US/US]; 184 Bittercreek Drive, Folsom, CA 95630 (US). (74) Agent: GERSTMAN, George, H.; Seyfarth, Shaw, Fairweather & Geraldson, 43rd floor, 55 East Monroe Street, Chicago, IL 60603-5803 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: ROTARY BLOOD PUMP**(57) Abstract**

An implantable rotary sealless blood pump is provided. The pump can include hydrodynamic, magnetic and hybrid, hydrodynamic/magnetic bearings and combinations thereof. The rotor can include a shaft or the pump can be made shaftless. Close clearances may be maintained between the housing and the rotor by offsetting magnets or offsetting magnets and motor stators.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CN	Cameroon	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

ROTARY BLOOD PUMP

FIELD OF THE INVENTION

The invention relates generally to the field of blood pumps. More
5 specifically, the invention pertains to pumps of rotary design, suitable for
implantation in humans.

BACKGROUND OF THE INVENTION

Ventricular assist devices ("VAD"), based on sealless rotary blood
10 pumps, do not have drive shafts for the transmission of torque. Transmission of
torque can readily be accomplished with the use of magnetic or electromagnetic
coupling, but supporting the impeller poses challenges because of the unique
properties of blood.

Blood can be used for hydrodynamic support and surface lubrication
15 in sealless rotary pumps. But, the use of blood for lubrication poses many
challenges not encountered with conventional lubricants such as oil, graphite, etc.
Blood is composed of cellular elements which can be adversely effected or
destroyed by mechanical forces and heat. In addition, blood carries large
molecules, such as proteins, enzymes and clotting precursors, which can be
20 damaged, denatured or inactivated as a result of heat, shear, material surfaces, or
bearing clearances found in rotary blood pumps. Also, the blood can form clots.

Thus, the use of blood for hydrodynamic support and surface
lubrication imposes a very narrow range of operating conditions. To avoid cell
injury, only very low levels of shear can be produced. To avoid protein
25 denaturation, local heats must not exceed 45 degrees C. To avoid the formation
of clots, surfaces must be made of blood compatible materials and rapid exchange
of blood within narrow clearances must be ensured.

Accordingly, it is an object of the present invention to provide a rotary blood pump using hydrodynamic bearings, magnet bearings, hybrid hydrodynamic/magnetic bearings or combinations thereof.

It is yet a further object of the present invention to provide a rotary
5 blood pump in which all the internal surfaces are regularly washed by fresh blood to prevent thrombosis from occurring.

It is another object of the present invention to provide a rotary blood pump which does not subject any blood to shear forces, temperatures or materials that would substantially damage blood or adversely react with blood.

10 It is another object of the present invention to provide a rotary blood pump in which the magnetic and hydrodynamic forces acting on the rotor provide sufficient support to allow elimination of the shaft.

Other objects and advantages will become apparent as the description proceeds.

15

SUMMARY OF THE INVENTION

In accordance with illustrative embodiments of the present invention, a rotary blood pump includes a pump housing and a rotor comprising an impeller within the housing. In some embodiments, the rotor also includes a shaft.

20 However, it is presently preferred to design the pump in order to eliminate the necessity for a shaft.

The rotor is suspended within the housing by magnetic and hydrodynamic forces or a combination of magnetic and hydrodynamic forces such that under normal conditions there is little or no rubbing contact between the
25 housing and the rotor. To that end, the pump is provided with hydrodynamic bearings, magnetic bearings, hybrid hydrodynamic/magnetic bearings and combinations of these types of bearings.

In certain embodiments of the invention, a rotary blood pump has a housing and a rotor within the housing. The rotor includes an impeller and a shaft. A radial bearing is provided using magnets carried on the shaft and magnets carried on the housing. A hydrodynamic thrust bearing is defined by a gap
5 between the impeller and the housing. A second radial bearing is defined by a gap between the impeller and an inward extension of the housing. The clearance in the gap of the second radial bearing is greater than the clearance in the hydrodynamic thrust bearing in order to provide for greater blood flow in this gap.

In other embodiments of the invention, a portion of one face of the
10 housing and a portion of one face of the impeller have complementary shaped surfaces and are separated by a gap with sufficient clearance that little or no radial hydrodynamic support is provided.

In other embodiments of the invention, the radial magnetic bearing in the area of the pump is eliminated. In certain of these embodiments, a rotary
15 blood pump has a pump housing and a rotor within the housing. The rotor includes an impeller and a shaft. A hydrodynamic thrust bearing is defined by a gap between the impeller and the housing. A hydrodynamic radial bearing in the area of the impeller is defined by a gap between the impeller and an inward extension of the housing.

20 In further embodiments of the invention, the rotary blood pump is made shaftless. In certain of these embodiments, a rotary blood pump has a pump housing and a rotor comprising an impeller. A hydrodynamic thrust bearing is defined by a gap between the impeller and the housing. A hydrodynamic radial bearing is defined by a gap between the impeller and an inward extension of said
25 housing.

In other embodiments of the invention employing a shaftless rotor, a magnetic radial bearing has one or more magnets carried by the impeller and one or more magnets carried by an inward extension of the housing. A hydrodynamic

thrust bearing is defined by a gap between the impeller and the housing.

In certain alternative embodiments of the invention, the clearance of the magnetic radial bearing is reduced so that the bearing provides additional, hydrodynamic support. In other embodiments, the rotary pump includes more than
5 one magnetic radial bearing each comprising one or more magnets carried by the impeller and one or more magnets carried by an inward extension of the housing.

In preferred embodiments of the present invention, the magnets and motor stators can be offset axially, radially or both to provide forces to hold the rotor and its parts in proper relation to the housing, to dampen or prevent eccentric
10 movement of the rotor, or to preload bearings to counteract hydrodynamic pressure. In certain of these preferred embodiments, magnets or motor stators in one part of the pump are offset in such a way to provide opposing forces to magnets or motor stators offset in another part of the pump.

The present invention incorporates new discoveries relating to non-
15 intuitive ways to support the rotor of a blood pump. One especially significant discovery relates to the improvements in the thrust bearings. It has been found that preloading the hydrodynamic thrust bearings by offsetting magnets or motor stators with approximately 1/2 to 3/4 lbs. of force, employing a large bearing surface, and providing for high flow through the bearing achieves substantial benefits. With
20 these improvements, the hydrodynamic thrust bearing provides an unexpected amount of both axial and moment-restoring force to support the rotor in the axial direction and to prevent tilting and eccentric motion of the rotor. The amount of support and stability is so substantial that it is possible to eliminate the forward magnetic bearings in the area of the pump inlet, and the shaft, spindle, spoke and
25 hub of the pump shown in U.S. Patent No. 5,840,070. Thus, the pump design can be simplified, the manufacturing costs can be reduced, and potentially stagnant areas in the pump can be eliminated.

Through the present invention, substantial improvements and benefits are also provided in the radial or journal bearings in the area of the impeller. The hybrid hydrodynamic/magnetic radial bearings of this invention allow large clearances and provide large blood flow in the journal area without
5 resulting in anticipated increases in blood damage due to shear. It is believed that the magnetic force decreases the load on the bearing and, thus, decreases shear. Any transient loads caused by eccentric movements are counteracted by the spring forces in hydrodynamic thrust bearings and the hydrodynamic and magnetic forces in the hybrid hydrodynamic/magnetic bearings in the journal area. Again, these
10 improvements in support for the rotor further allow for elimination of any forward magnetic bearings and the shaft, spindle, spoke and hub.

Indeed, the support and restoring and stabilizing forces provided by the present invention are so substantial that it is deemed possible to adjust these forces to provide a rotor with motion that has a controlled amount of eccentricity
15 radially, axially or both. If the motion of the rotor is not perfectly circular, further increases in the exchange of blood in the bearings can be achieved.

A more detailed explanation of the invention is provided in the following description and claims, and is illustrated in the accompanying drawings.

20

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a left front perspective of an illustrative embodiment of the blood pump of the present invention;

Fig. 2 is a simplified, fragmentary, representation of a human heart, showing the pump implanted within the left ventricle of the heart;

25

Fig. 3 is a longitudinal, cross-sectional view of a simplified, schematic representation of an illustrative embodiment of the pump;

Fig. 3A is an enlarged view of the circled portion 3A from Fig. 3;

Fig. 4 is a cross-sectional end view of the Fig. 3 pump with the end of the housing removed for clarity;

Fig. 5 is a perspective view, partially broken for clarity, of the blood pump of Fig. 3;

5 Fig. 5A is a perspective view of a portion of Fig. 5, showing the slotted motor stator;

Fig. 5B is a perspective view, similar to Fig. 5A but showing a slotless motor stator;

Fig. 6 is another perspective view, partially broken for clarity, of
10 the blood pump of Fig. 3;

Fig. 7 is a longitudinal, cross-sectional view of another embodiment of the pump;

Fig. 7A is an enlarged view of the circled portion 7A of Fig. 7.

Fig. 8 is a longitudinal, cross-sectional view of another embodiment
15 of the pump;

Fig. 8A is an enlarged view of the circled portion 8A of Fig. 8;

Fig. 9 is a longitudinal, cross-sectional view of another embodiment of the pump;

Fig. 9A is an enlarged view of the circled portion 9A of Fig. 9;

20 Fig. 10 is a longitudinal, cross-sectional view of another embodiment of the pump;

Fig. 10A is an enlarged view of the circled portion 10A of Fig. 10;

Fig. 11 is a longitudinal, cross-sectional view of another embodiment of the pump;

25 Fig. 11A is an enlarged view of the circled portion 11A of Fig. 11;

Fig. 12 is a longitudinal, cross-sectional view of another embodiment of the pump;

Fig. 12A is an enlarged view of the circled portion 12A of Fig. 12;

Fig. 13 is a longitudinal, cross-sectional view of another embodiment of the pump;

Fig. 13A is an enlarged view of the circled portion 13A of Fig. 13;

Fig. 14 is a front, perspective view of a rotor having a shaft and an
5 impeller;

Fig. 15 is an end view of a rotor having a shaft and an impeller; and

Fig. 16 is an enlarged fragmentary view of the end of the impeller.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

10 The illustrative embodiments of this invention represent presently preferred improvements and advances over the devices described and claimed in U.S. Patent No. 5,840,070 issued November 24, 1998. Although the entire disclosure of U.S. Patent No. 5,840,070 is hereby incorporated by reference
15 understanding the description of the preferred embodiments of the present invention.

Referring to Fig. 1 of the drawings, a rotary blood pump 10 includes a housing having an elongated inlet tube 12 and an impeller casing or volute 14. A discharge tube 16 extends through the housing to communicate with the interior
20 of impeller casing 14. Discharge tube 16 has a tangential orientation.

A presently preferred arrangement for the anatomical placement of the pump 10 is shown in Fig. 2. The simplified representation of a heart 18 includes a left ventricle 20 and an aorta 22. The inlet tube 12 serves as the inflow cannula and is placed into the apex of the left ventricle 20. An arterial vascular
25 graft 24 is connected on one end to discharge tube 16 and on the other end of the aorta 22 through an end to side anastomosis. The pump 10 is connected by means of insulated cable 26 to a controller 28 and a power supply 30. It is contemplated that controller 28 and power supply 30 may be worn externally or, alternatively,

may be implanted. Rather than using wires, transcutaneous controller and power transmission could be used.

Referring to Figs. 3, 3A, 4, 5 and 6, pump rotor 32 includes an elongated, cylindrical support shaft or spindle 34 attached to impeller 36. The
5 rotor 32 is mounted for rotation about an longitudinal axis which extends both through shaft 34 and impeller 36.

This embodiment includes a forward magnetic bearing 38. The forward magnetic bearing 38 includes a plurality of rings of axially polarized permanent magnets 40 carried on the inlet tube 12 of the housing and a plurality
10 of rings of axially polarized, disc-shaped, permanent magnets 42 carried on the shaft 34 of the rotor 32.

In the Figs. 3-6 embodiment, a first motor stator 44 comprising conductive coils or motor windings 46 is located at the rear of casing 14. A ring of backiron 48 is located behind windings 46. First motor stator 44 and backiron
15 48 are fixed between outside wall of the housing 50 and the inside wall of the housing 52.

A second motor stator 54 comprising windings 56 is positioned on the forward side of casing 14. Windings 56 are fixed to the inside wall of housing 52 of the impeller casing 14 and a ring of backiron 58 is positioned forward of
20 windings 56. As illustrated in Figs. 5, 5A and 6, backiron 48 and backiron 58 have teeth 60 which extend into the stator windings to form the stator iron. Thus the windings 56 wrap around the teeth 60 in the intervening slots 62 (See Fig. 5A). In the Fig. 5B embodiment, a slotless motor stator is illustrated. In that embodiment, the windings 46 are fixed to the backiron 48 and there are no teeth
25 extending into the stator windings.

It can be seen that the motor stators 44 and 54 are placed on opposite sides of casing 14 such that each is adjacent to the pole faces of the motor rotor magnets 64. Backiron 48 and backiron 58 serve to complete a magnetic circuit.

The windings 46 and 56 of the stators 44, 54 can be in series or each stator 44, 54 can be commutated independent of the other. There are several advantages to this approach.

First, as long as the pole faces of the motor rotor magnets are
5 centered between the faces of the motor stators, the net axial force will be relatively low.

Second, the radial restoring force which results from the attractive force of the motor rotor magnets to the motor stators will be nearly twice as large as the restoring force with only one stator. The total volume and weight of the
10 motor will be smaller than a single stator design.

Third, the dual stator design is adapted to provide system redundancy for a fail safe mode, since each stator can be made to operate independently of the other in the case of a system failure.

Fourth, hydrodynamic bearings can be located on the surface of the
15 impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device. Referring to Figures 3 and 3a in particular, hydrodynamic bearings in the form of raised pads 66, 68 and contact surfaces 70 and 72 are illustrated. Such hydrodynamic bearings are symmetrically located about the impeller as illustrated in Figure 5 in which raised pads 66 are
20 shown.

The raised pads could be rectangularly-shaped or wedge-shaped and are preferably formed of hardened or wear resistant materials such as ceramics, diamond coatings or titanium nitride. Alternatively, the raised pads may be formed of a different material having an alumina or other ceramic coating or insert.

25 The raised pads are carried by either the impeller or the casing, or an attachment to the casing. In the Figures 3 and 3a embodiment, the raised pads 66 are carried by the impeller and the raised pads 68 are carried by a cup-shaped member 74 that is fastened to the casing in the journal area of the pump. Cup-

shaped member 74 is utilized as a reinforcement for the casing which would not be structurally stable enough to carry the raised pads itself.

The hydrodynamic bearings are formed by a raised pad spaced from a contact surface by the blood gap. Although at rest there may be contact between the impeller and the casing, once rotation begins each hydrodynamic bearing is structured so that, during relative movement between the raised pad and the contact surface, the hydrodynamic action of the fluid film produces increased pressure within the bearing gap which forces the raised pad and the contact surface apart.

Depending upon the location of the hydrodynamic bearings, they can aid in axial support, radial support or both axial and radial support. For example, if the bearings are perpendicular to the rotational axis, they aid primarily in axial support but if they are at an angle with respect to the rotational axis, they aid in both radial and axial support. In the embodiment of Figures 3-6, the hydrodynamic bearings are positioned outside the axis of rotation, as illustrated.

Referring to Fig. 4 an impeller 36 is shown therein having a number of blade sectors 76, 78 and 80. Blade sectors 76 and 78 are separated by slot 82; blade sectors 78 and 80 are separated by slot 84; and blade sectors 80 and 76 are separated by slot 86. By utilizing blade sectors 76, 78 and 80 that are relatively thick in the axial direction, narrow and deep impeller blood flow paths are formed by slots 82, 84 and 86 between the adjacent edges of the blade sectors. By increasing the thickness of the blade sectors and narrowing the blood passageway, the ratio between the area of working surface of the blades and the volume of the passageway is increased. Also the average distance of the liquid in the passageway from the working surface of the blades is decreased. Both of these beneficial results allow a small pump for blood which has less blades for potentially damaging blood, yet the small pump maintains acceptable efficiency. Another benefit of the thick impeller is the ability to utilize magnetic pieces 88 that are inserted in a manner enabling the stators to be on opposite sides of the impeller.

Another embodiment of the blood pump 10 is shown in Figs. 7 and 7A. This embodiment includes forward magnetic bearing 38 including a plurality of magnets 40 carried on the inlet tube 12 of the housing and a plurality of magnets 42 carried on the shaft 34. As best shown in Fig. 7A, this embodiment includes at least one hydrodynamic thrust bearing defined by a gap 88 between the impeller 36 and the housing. This embodiment also includes at least one radial bearing defined by a gap 90 between the impeller 36 and an inward extension of the housing in the journal area. The minimum clearance in gap 88 is about 0.0005-0.0015 inches and in gap 90 is about 0.006-0.020 inches.

10 The housing includes a hard, smooth, ceramic surface 92 in the area of the impeller 36 which extends forward into the area of the shaft 34. The ceramic surface 92 prevents contact between blood and the metal parts mounted on the housing such as, for example, magnets, motor coils and backirons and protects the housing in case of contact between the rotor and the housing. In certain 15 embodiments, it may be preferable to make the entire housing out of ceramic or to make the entire outer and inner surfaces of the housing out of ceramic.

Another embodiment of the blood pump 10 is shown in Figs. 8 and 8A. This embodiment differs from the embodiment of Figs. 7 and 7A in that the gap 94 between complementary-shaped surfaces on a rear portion of the inside face 20 of the housing and a portion of the rear face of the impeller 36 in the journal area has sufficient clearance such that this gap does not under normal operating conditions provide radial, hydrodynamic support. The minimum clearance in gap 94 is at least about 0.010 inch.

Another embodiment of the blood pump 10 is shown in Figs. 9 and 25 9A. In this embodiment, the shaft 34 of the rotor 32 is shortened and there are no forward radial bearings or related magnets. In this embodiment, a hydrodynamic thrust bearing is defined by a gap 88 between the impeller and the housing. A hydrodynamic, radial bearing is defined by a gap 96 between the impeller 36 and

an inward extension of the housing in the journal area. The minimum clearances in the gap 88 and in the gap 96 are about 0.0005-0.0015 inches.

Another embodiment of the blood pump 10 is shown in Figs. 10 and 10A. In this embodiment, the shaft of the rotor is eliminated. Therefore, the rotor comprising the impeller 36 is a ring. As in the embodiment of Figs. 9 and 9A, a hydrodynamic, thrust bearing is defined by a gap 88 between the impeller and the housing and a hydrodynamic, radial bearing is defined by a gap 96 between the impeller 36 and an inward extension of the housing in the journal area. The minimum clearances in gaps 88 and 96 are about 0.0005-0.0015 inches.

10 Another embodiment of the blood pump 10 is shown in Figs. 11 and 11A. In this embodiment, the rotor is shaftless and the rotor comprises a ring-shaped impeller 36. A magnetic radial bearing comprises one or more magnets 98 carried on the impeller 36 and one or more magnets 100 carried on an inward extension 102 of the housing in the journal area. In Fig. 11, the magnetic radial bearing and the magnets 98 and the magnets 100 are shown adjacent the rear end of the impeller 36. This magnetic bearing could, of course, be placed in the center of the impeller, adjacent the forward end of the impeller or elsewhere as long as radial support for the rotor is provided. The gap 104 between the impeller 36 and the inward extension 102 of the housing has a minimum clearance of 0.003 inch and a preferred clearance of 0.006-0.020 inches. A hydrodynamic thrust bearing is defined by the gap 88 with a clearance of 0.0005-0.0015 inches.

One presently contemplated alternative to the embodiment shown in Figs. 11 and 11A has a gap with a clearance of 0.002-0.008 inches between the impeller 36 and the inward extension 102 of the housing in the location of gap 104. 25 With this clearance, the gap would define a hydrodynamic, magnetic radial bearing in the journal area.

Another presently contemplated alternative to the embodiment shown in Figs. 11 and 11A is shown in Figs. 12 and 12A. In this embodiment, the

hydrodynamic bearing defined by the gap 88 is adjacent the front side (i.e., the direction of the pump inlet) of the impeller 36. It is believed that placement of the hydrodynamic bearing in this forward position could also be beneficial in the other embodiments shown herein.

5 Another embodiment of the blood pump 10 is shown in Figs. 13 and 13A. This embodiment is shaftless and there are two magnetic radial bearings comprising two sets of magnets 98 carried on the impeller 36 and two sets of magnets 100 carried on an inward extension of the housing in the journal area. The gap 104 between the impeller 36 and the inward extension 102 of the housing has
10 a minimum clearance of 0.003 inch. A hydrodynamic thrust bearing is defined by a gap 88 with a clearance of 0.0005-0.0015 inches.

It should be understood that the clearances for the gaps set forth in this application are approximate clearances anticipated during normal operation of the pumps of the present invention and therefore represent minimum film
15 thicknesses. When a pump is not running, is starting up, and other abnormal conditions, the clearances in the gaps will be different. When the magnets or motor stators are offset to provide a preload force on a bearing, there may be zero clearance between parts of the rotor and the housing when the pump is not running.

Figs. 14, 15 and 16 provide details of preferred embodiments of the
20 rotor 32 including the shaft 34 and the impeller 36 in order to show features which are incorporated to ensure effective movement of blood. In this particular embodiment, the impeller 36 has four blade sectors 106, 108, 110 and 112. The blade sectors 106, 108, 110 and 112 are separated by slots 114, 116, 118 and 120. As best shown in Fig. 15, the shaft 34 includes flow passages 122, 124, 126 and
25 128. In addition, a fluid-drive channel 130 is provided in shaft 34. The slots 122, 124, 126, 128 and the channel 130 are designed in order to keep blood from stagnating and clotting in areas near and around the shaft 34. In the shaftless embodiments, these features would not be present and there would be a straight

circular bore through the center of the impeller.

The impeller 36 includes, on the faces of its blades defining the hydrodynamic thrust bearing, tapered surfaces 132, 134, 136 and 138 in the end of each blade 106, 108, 110 and 112. The tapered surfaces 132, 134, 136 and 138 are of maximum depth at leading edges of the blades and gradually decrease in depth. These tapered surfaces 132, 134, 136 and 138 are designed to ensure blood moves through the gap 88 in and feed the hydrodynamic thrust bearing created in this gap 88. At the periphery of the tapered surfaces 132, 134, 136 and 138, the impeller 36 is provided with shrouds or end walls 140 to channel blood into and through the hydrodynamic thrust bearings.

Various specific combinations of hydrodynamic, magnetic and hybrid hydrodynamic/magnetic bearings have been described. It is contemplated that other combinations would be useful and should be considered to be within the scope of the invention.

Although illustrative embodiments of the invention have been shown and described, it is to be understood that various modifications and substitutions may be made by those skilled in the art without departing from the novel spirit and scope of the present invention.

WHAT IS CLAIMED IS:

1. A rotary blood pump comprising:
 - a pump housing;
 - 5 a rotor within said housing and comprising an impeller and a shaft;
 - a radial bearing comprising magnets carried on said shaft and magnets carried on said housing;
 - at least one hydrodynamic thrust bearing defined by a gap between the impeller and the housing; and
 - 10 at least one radial bearing defined by a gap between the impeller and an inward extension of said housing with greater clearance than the clearance of said hydrodynamic thrust bearing.
2. The rotary blood pump of claim 1 wherein the minimum clearance
 - 15 in the gap defining the hydrodynamic thrust bearing is about 0.0005-0.0015 inches.
3. The rotary blood pump of claim 2 wherein the minimum clearance
 - in the gap defining the radial bearing is about 0.006-0.020 inches.
- 20 4. The rotary blood pump of claim 1 wherein said magnets carried on said shaft and said magnets carried on said housing comprising said radial bearing are axially offset with respect to each other.
- 25 5. The rotary blood pump of claim 1 further comprising one or more magnets and one or more motor stators which are offset with respect to each other.

6. The rotary blood pump of claim 1 wherein said magnets carried on said shaft and said magnets carried on said housing comprising said radial bearing are offset with respect to each other and wherein one or more magnets and one or more motor stators are offset with respect to each other in order to provide
5 opposing forces.

7. A rotary blood pump comprising:
a pump housing;
a rotor within said housing and comprising an impeller and a shaft:
10 a radial bearing comprising magnets carried on said shaft and magnets carried on said housing;
at least one hydrodynamic thrust bearing defined by a gap between the impeller and the housing; and
wherein at least a portion of one face of the housing and at least a portion of one
15 face of the impeller comprise complementary shaped surfaces defining a gap with sufficient clearance such that said gap does not provide radial hydrodynamic support.

8. The rotary blood pump of claim 7 wherein the minimum clearance
20 in the gap defining the hydrodynamic thrust bearing is about 0.0005-0.0015 inches.

9. The rotary blood pump of claim 7 wherein the minimum clearance in the gap defining said complementary surfaces is about 0.006-0.020 inches.

25 10. The rotary blood pump of claim 7 wherein the minimum clearance in the gap defining said complementary surfaces is at least about 0.010 inch.

11. The rotary blood pump of claim 7 wherein said magnets carried on said shaft and said magnets carried on said housing comprising said radial bearing are axially offset with respect to each other.

5 12. The rotary blood pump of claim 7 further comprising one or more magnets and one or more motor stators which are offset with respect to each other.

10 13. The rotary blood pump of claim 7 wherein said magnets carried on said shaft and said magnets carried on said housing comprising said radial bearing are offset with respect to each other and wherein the one more magnets and one or more motor stators are offset with respect to each other to provide opposing forces.

15 14. A rotary blood pump comprising:
a pump housing;
a rotor within said housing and comprising an impeller and a shaft;
at least one hydrodynamic thrust bearing defined by a gap between the impeller and the housing; and
20 at least one hydrodynamic radial bearing defined by a gap between the impeller and an inward extension of said housing.

15 15. The rotary blood pump of claim 13 wherein the minimum clearance in the gap defining the hydrodynamic thrust bearing is about 0.0005-0.0015 inches.

16. The rotary blood pump of claim 13 wherein the minimum clearance in the gap defining the hydrodynamic radial bearing is about 0.0005-0.0015 inches.

5 17. The rotary blood pump of claim 13 further comprising one or more magnets and one or more motor stators which are offset with respect to each other.

18. A shaftless rotary blood pump comprising:
10 a pump housing;
 a rotor comprising an impeller;
 at least one hydrodynamic thrust bearing defined by a gap between the impeller and the housing; and
 at least one hydrodynamic radial bearing defined by a gap between the impeller
15 and an inward extension of said housing.

19. The shaftless rotary blood pump of claim 18 wherein the minimum clearance in the gap defining the hydrodynamic thrust bearing is about 0.0005-0.0015 inches.
20

20. The shaftless rotary blood pump of claim 18 wherein the minimum clearance in the gap defining the hydrodynamic radial bearing is about 0.0005-0.0015 inches.

25 21. The shaftless rotary blood pump of claim 18 further comprising one or more magnets and one or more motor stators which are offset with respect to each other.

22. A shaftless rotary blood pump comprising:

a pump housing;

a rotor comprising an impeller;

at least one magnetic radial bearing comprising one or more magnets carried by
5 said impeller and one or more magnets carried by an inward extension of said
housing; and

at least one hydrodynamic thrust bearing defined by a gap between the impeller
and the housing.

10 23. The shaftless rotary blood pump of claim 22 wherein the
minimum clearance in the gap defining said magnetic radial bearing is about 0.003
inch.

24. The shaftless rotary blood pump of claim 22 wherein the
15 minimum clearance in the gap defining said magnetic radial bearing is about 0.006-
0.020 inches.

25. The shaftless rotary blood pump of claim 22 wherein the
minimum clearance in the gap defining said hydrodynamic thrust bearing is about
20 0.0005-0.0015 inches.

26. The shaftless rotary blood pump of claim 22 further comprising
one or more magnets and one or more motor stators which are offset with respect
to each other.

25

27. A shaftless rotary blood pump comprising:

a pump housing;

a rotor comprising an impeller;

at least one hydrodynamic, magnetic radial bearing comprising one or more magnets carried by said impeller and one or more magnets carried by an inward extension of said housing; and

5 at least one hydrodynamic thrust bearing defined by a gap between the impeller and the housing.

28. The shaftless rotary blood pump of claim 27 wherein the minimum clearance in the gap defining said hydrodynamic, magnetic radial bearing is about 0.002-0.008 inches.

10

29. The shaftless rotary blood pump of claim 27 wherein the minimum clearance in the gap defining said hydrodynamic thrust bearing is about 0.0005-0.0015 inches.

15

30. The shaftless rotary blood pump of claim 27 further comprising one or more magnets and one or more motor stators which are offset with respect to each other.

31. A shaftless rotary blood pump comprising;

20 a pump housing;

a rotor comprising an impeller;

at least two magnetic radial bearings each comprising one or more magnets carried by said impeller and one or more magnets carried by an inward extension of said housing; and

25 at least one hydrodynamic thrust bearing defined by a gap between the impeller and the housing.

32. The shaftless rotary blood pump of claim 31 wherein the minimum clearance in the gap defining said magnetic radial bearings is about 0.010 inch.

5 33. The shaftless rotary blood pump of claim 31 wherein the minimum clearance in the gap defining said hydrodynamic thrust bearing is about 0.0005-0.0015 inches.

10 34. The shaftless rotary blood pump of claim 31 further comprising one or more magnets and one or more motor stators which are offset with respect to each other.

FIG. 1

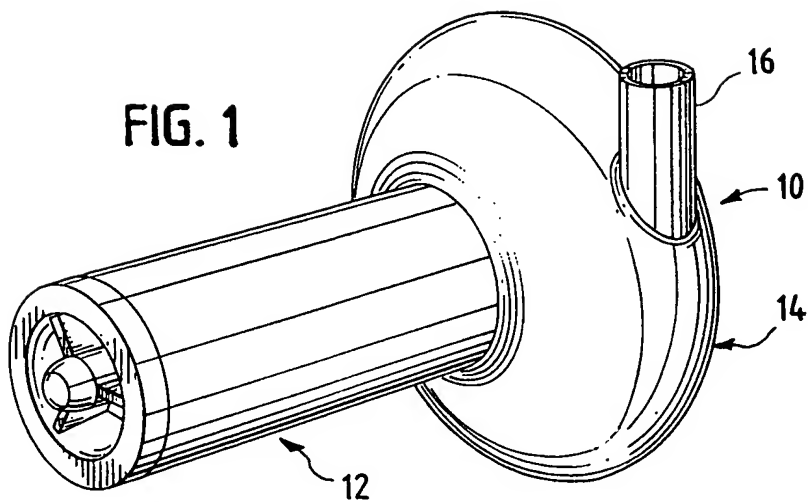
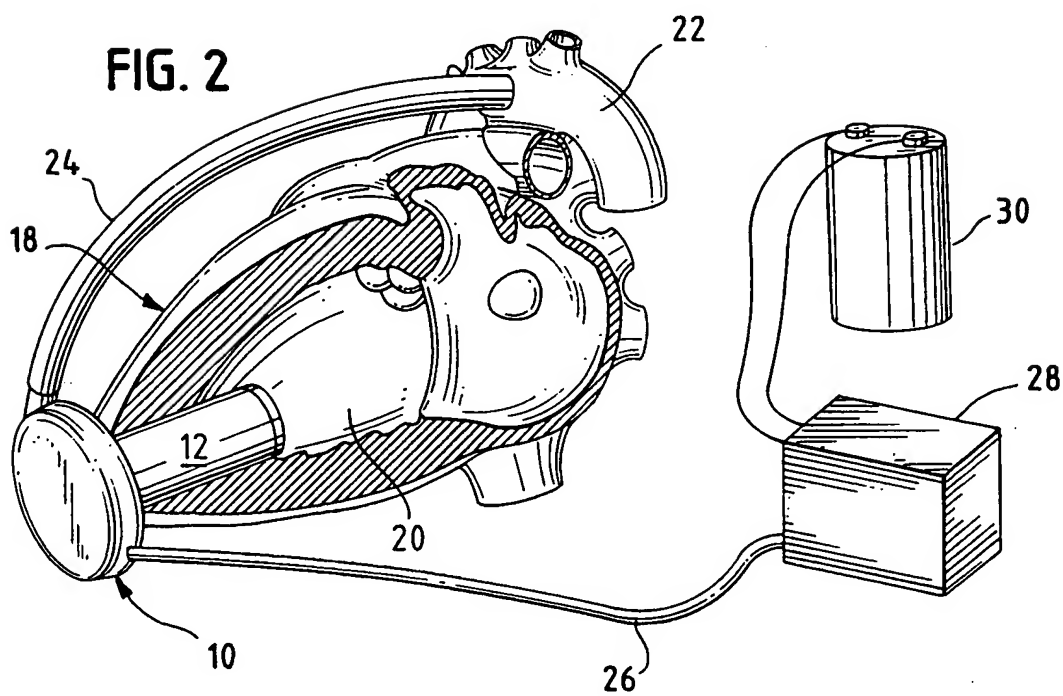


FIG. 2



2/14

FIG. 3

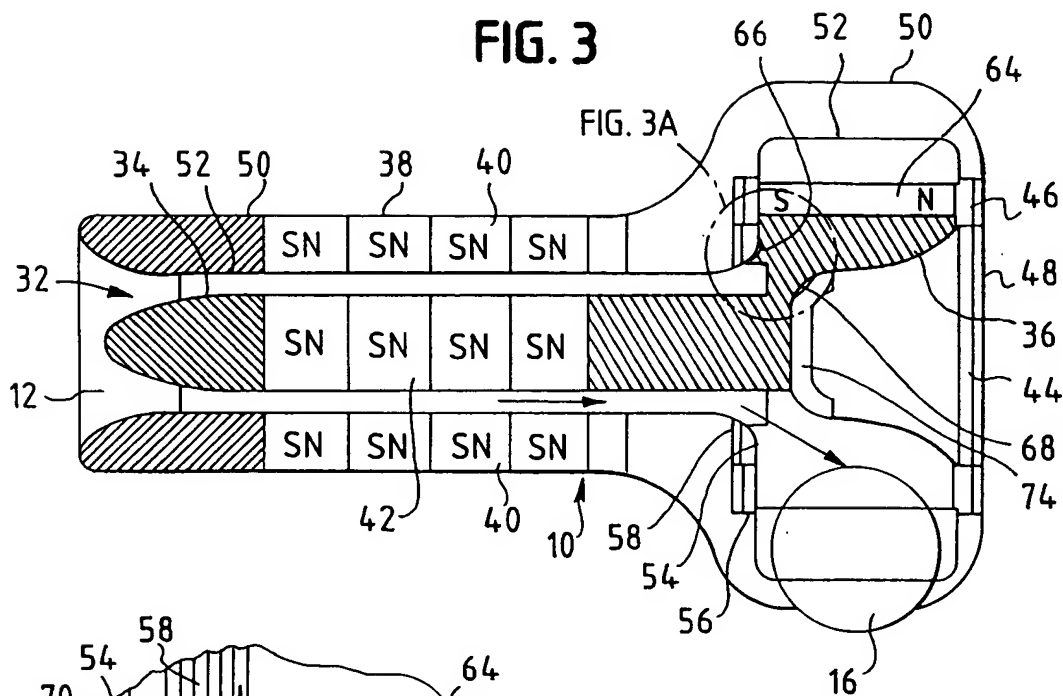


FIG. 3A

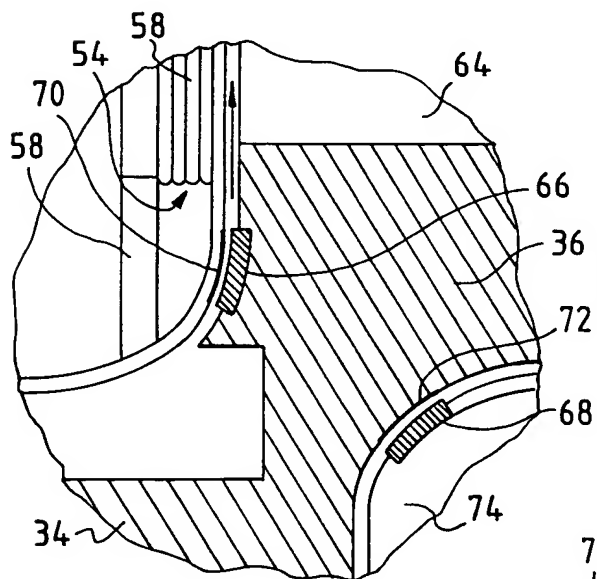
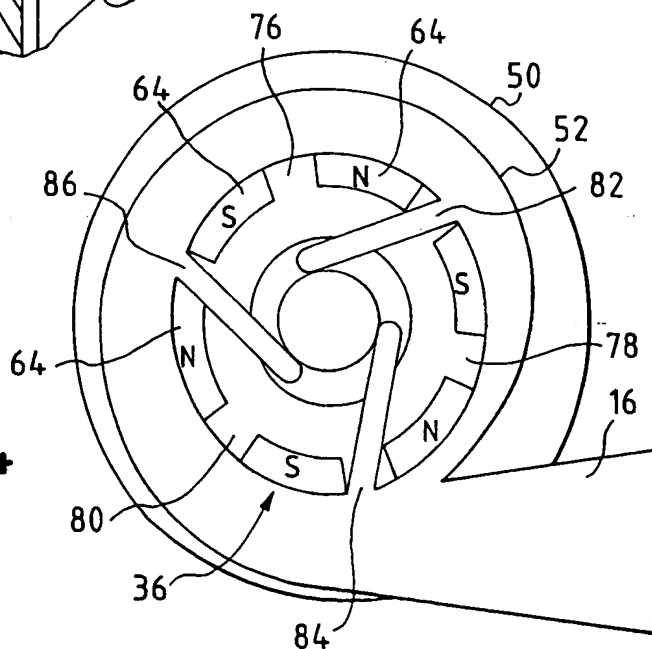


FIG. 4



BEST AVAILABLE COPY

3/14

BEST AVAILABLE COPY

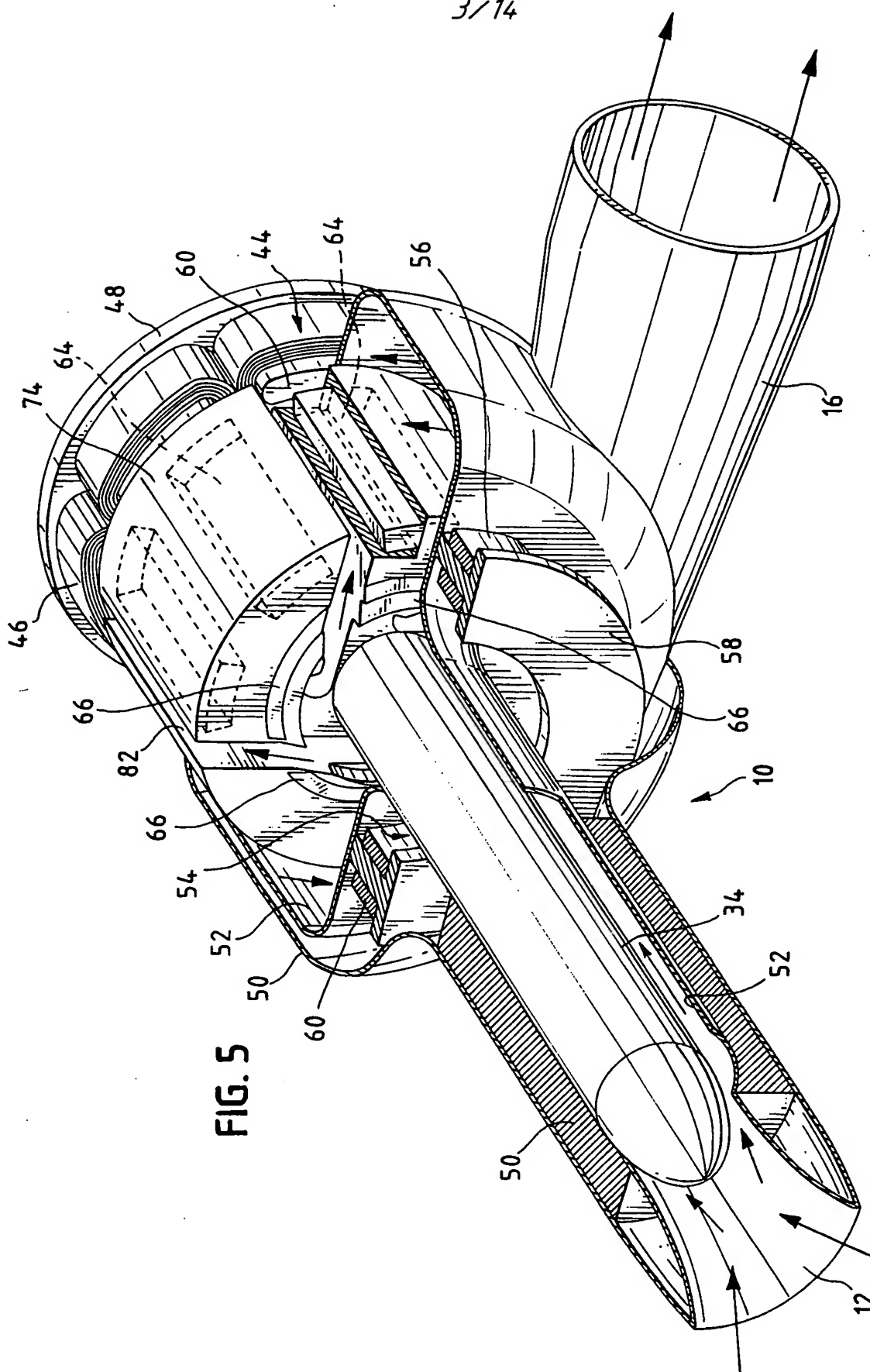


Fig. 5

4/14

FIG. 5A

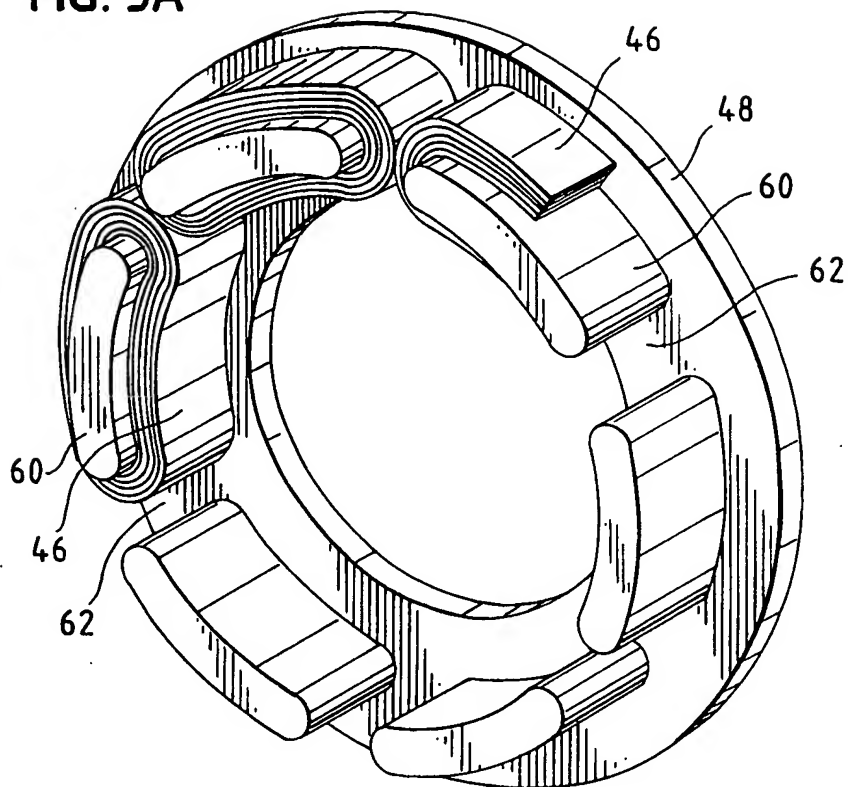
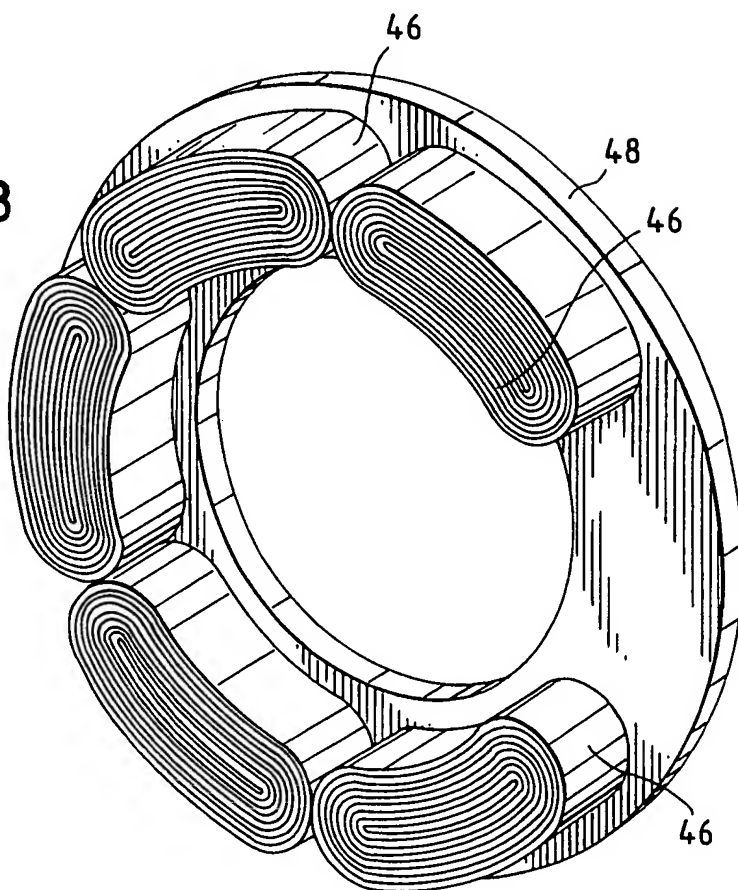


FIG. 5B



UNAVAILABLE COPY

BEST AVAILABLE COPY

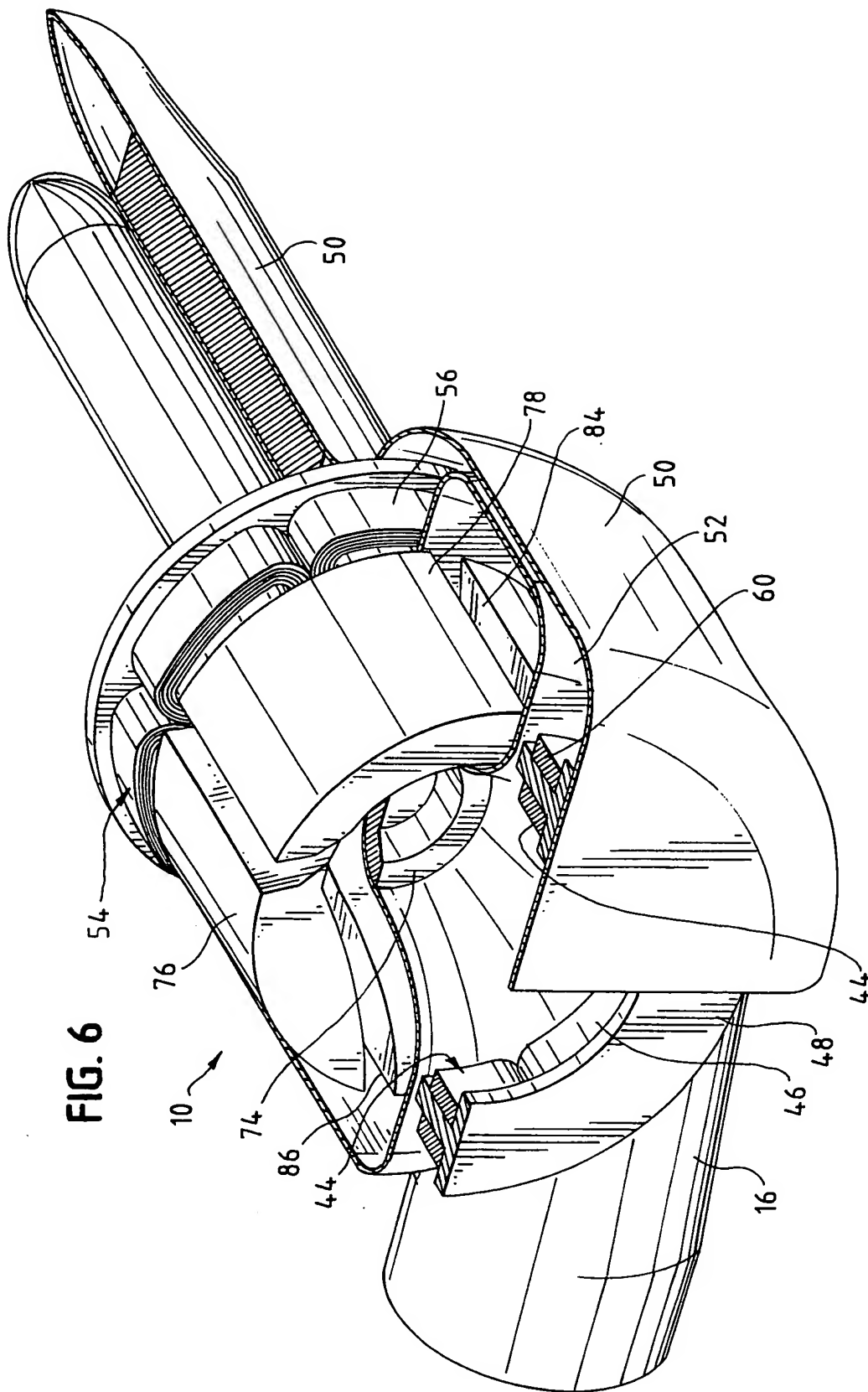


FIG. 7

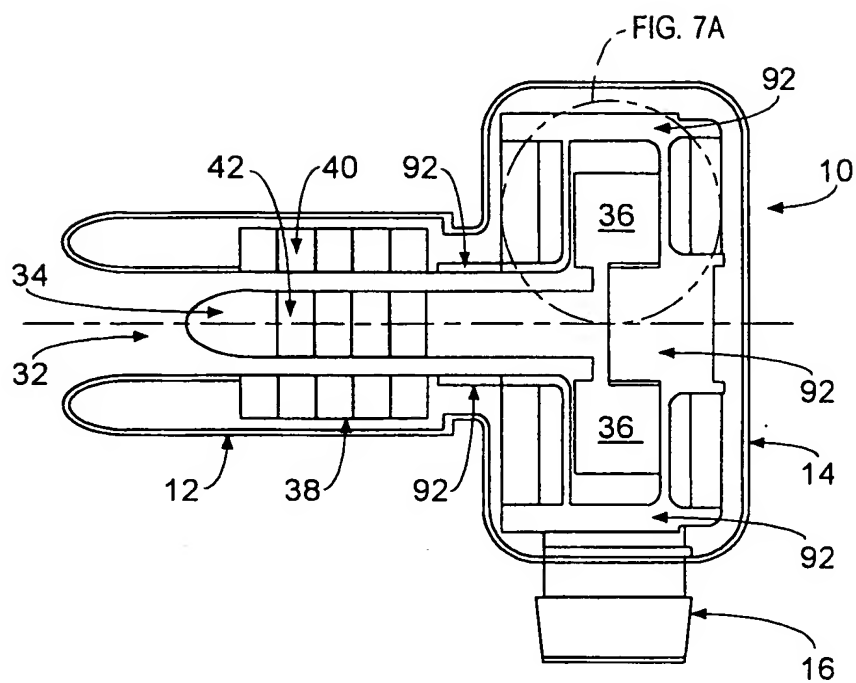
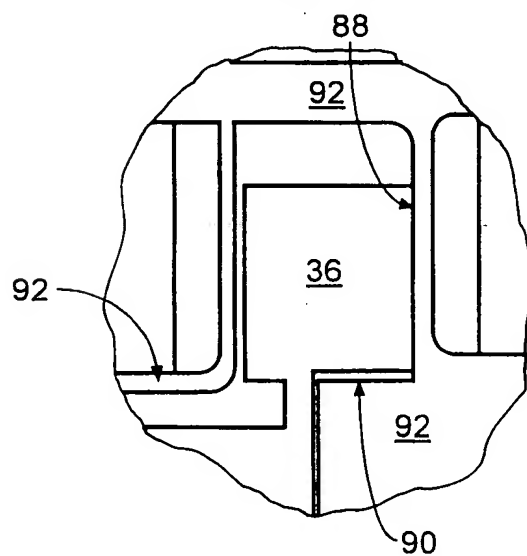


FIG. 7A



BEST AVAILABLE COPY

FIG. 8

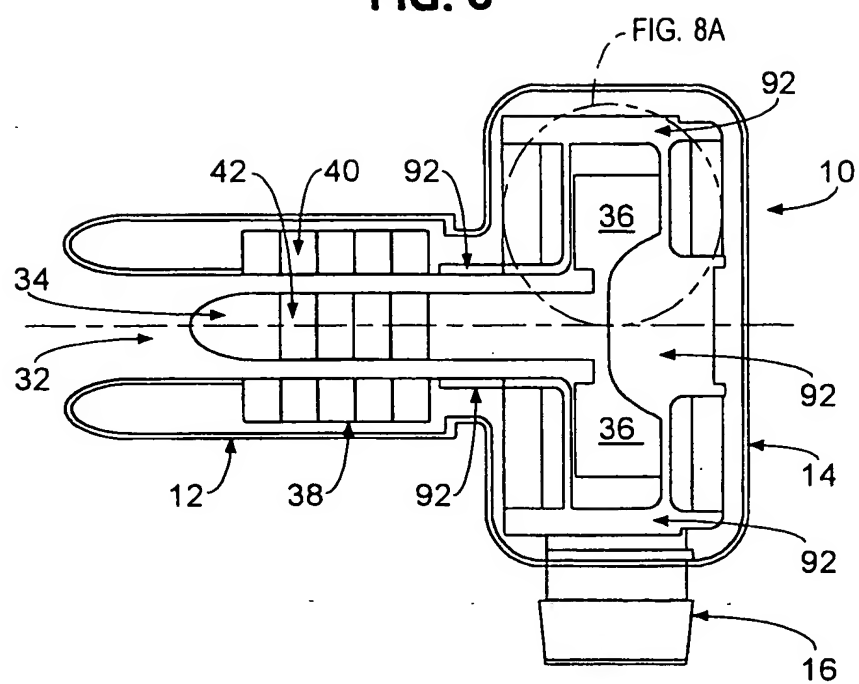
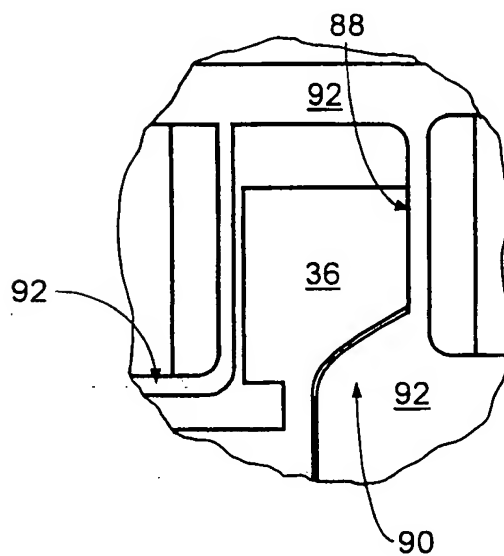


FIG. 8A



BEST AVAILABLE COPY

8/14

FIG. 9

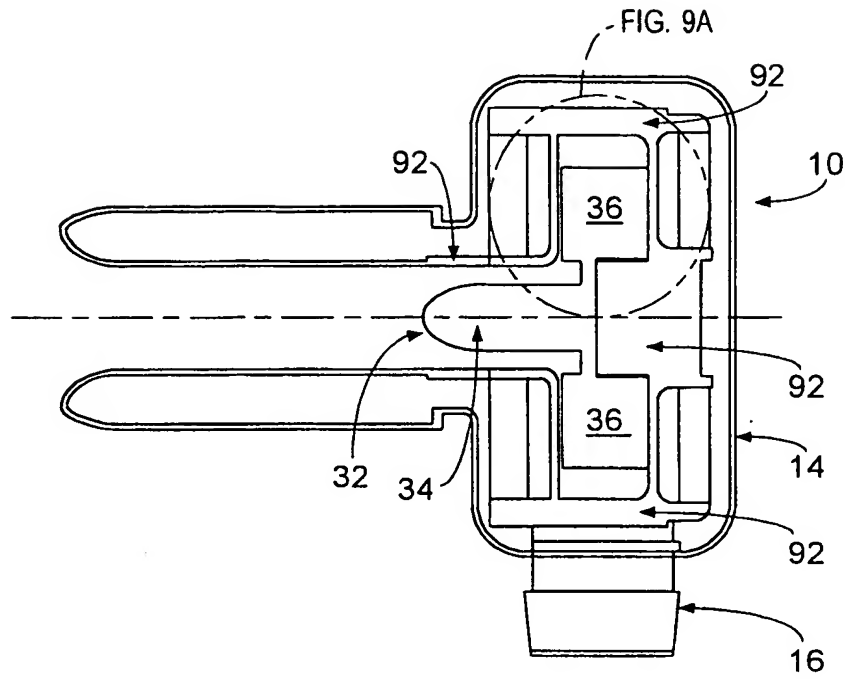
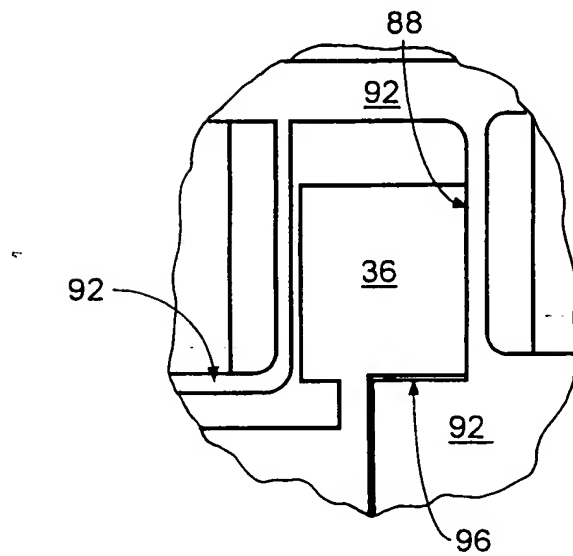


FIG. 9A



BEST AVAILABLE COPY

9/14

FIG. 10

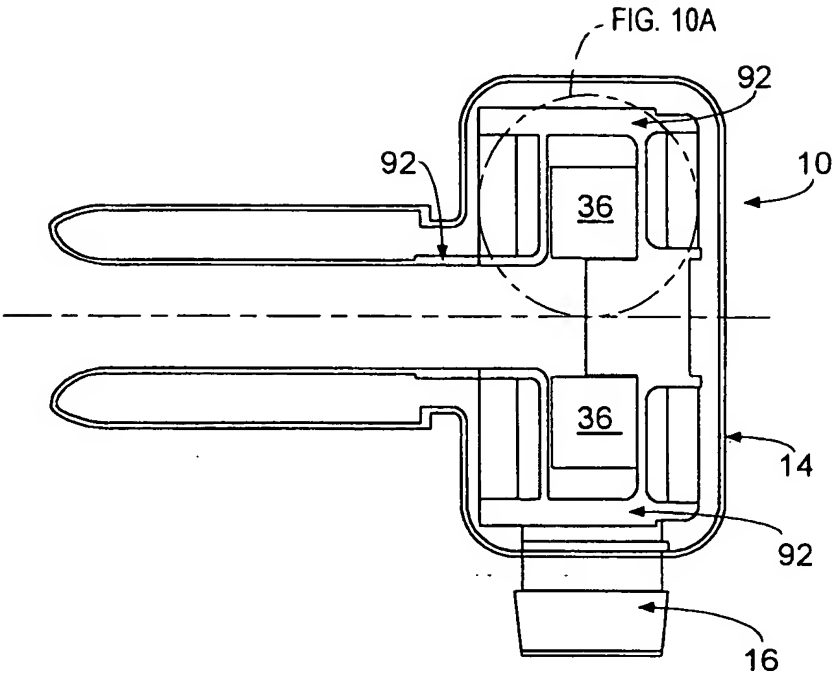
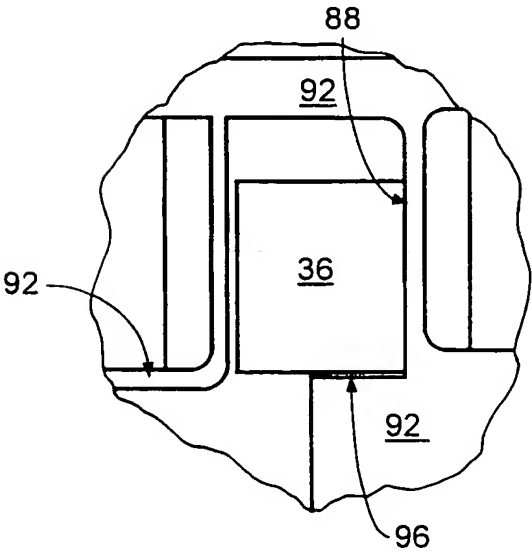


FIG. 10A



BEST AVAILABLE COPY

10/14

FIG. 11

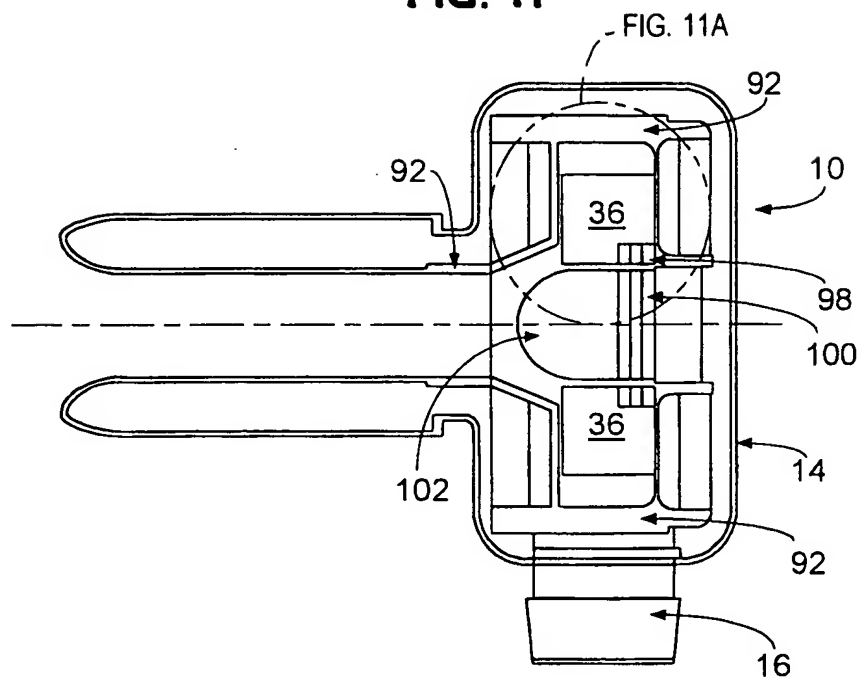
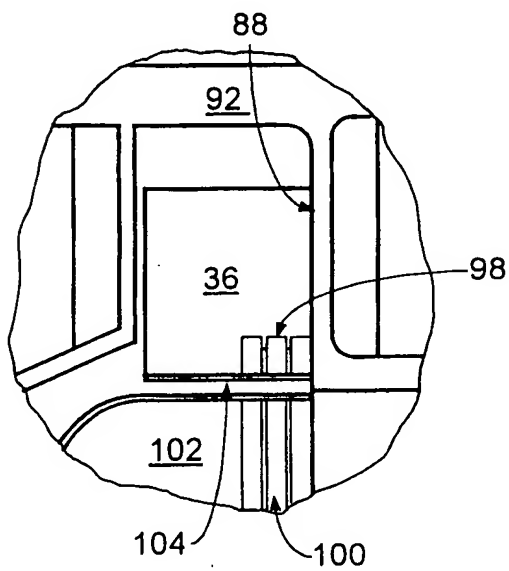


FIG. 11A



BEST AVAILABLE COPY

FIG. 12

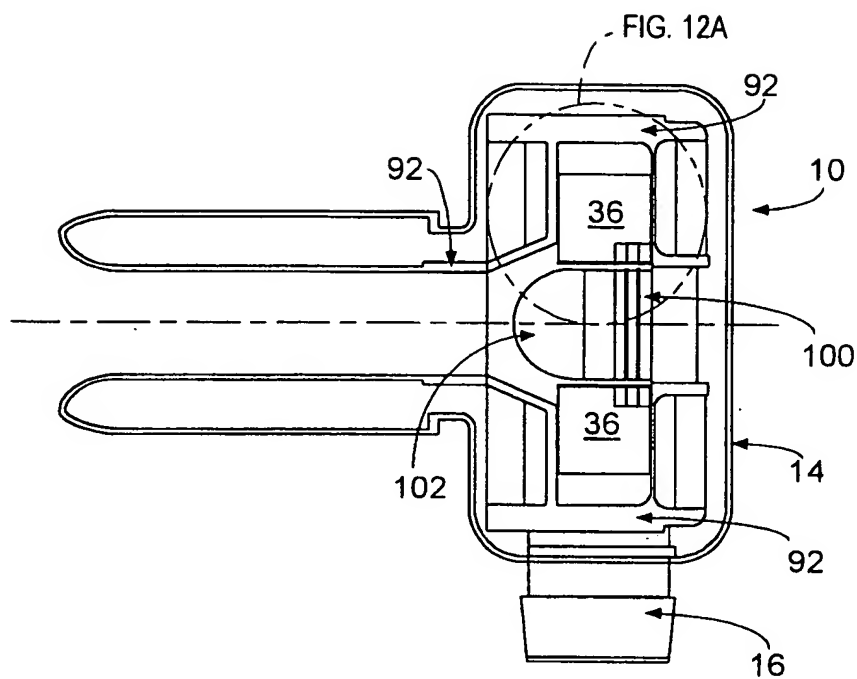
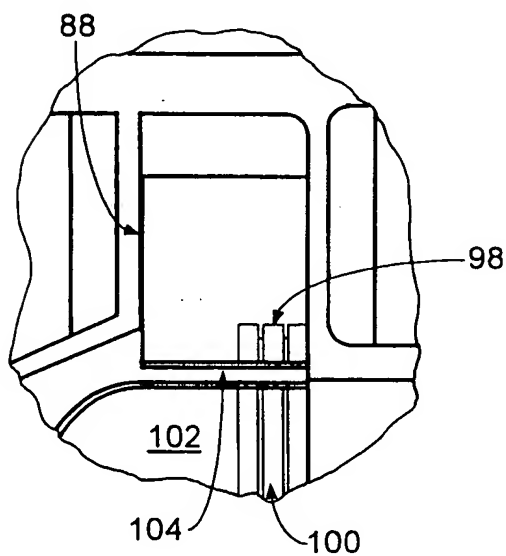


FIG. 12A



12/14

FIG. 13

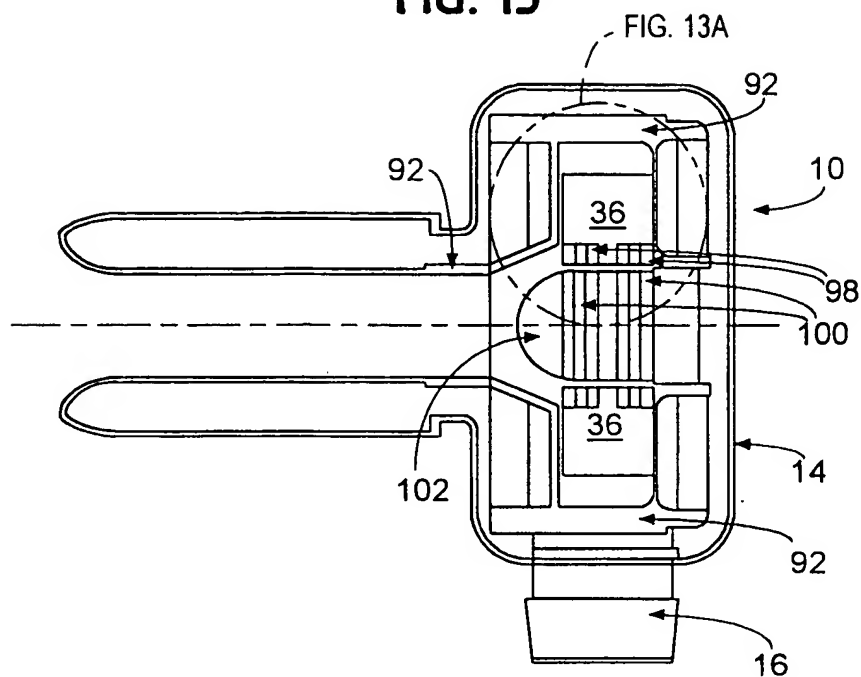
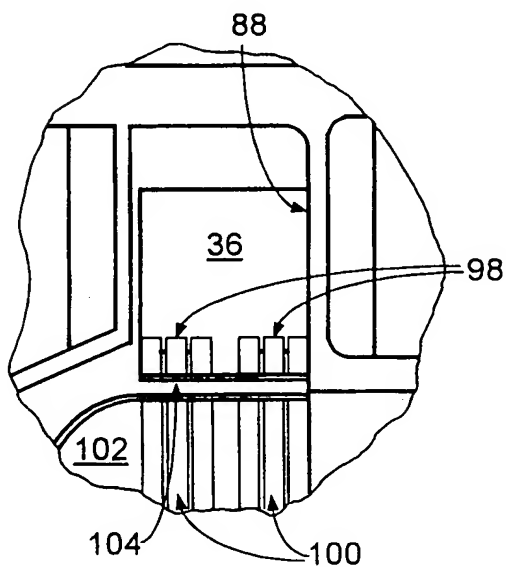


FIG. 13A



BEST AVAILABLE COPY

13/14

FIG. 14

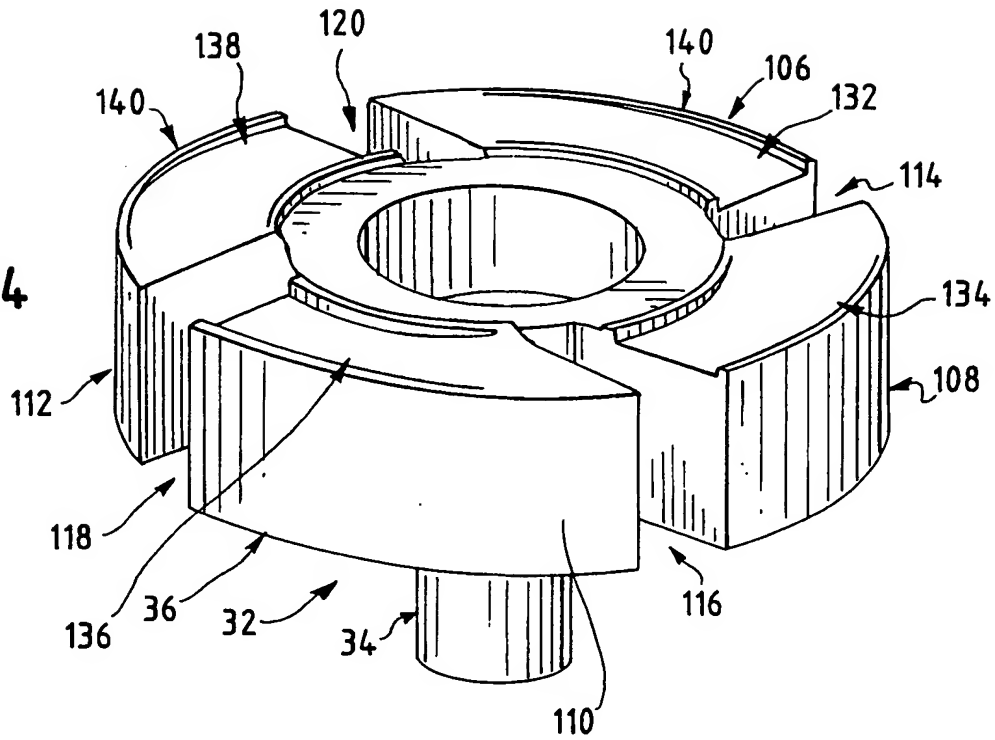
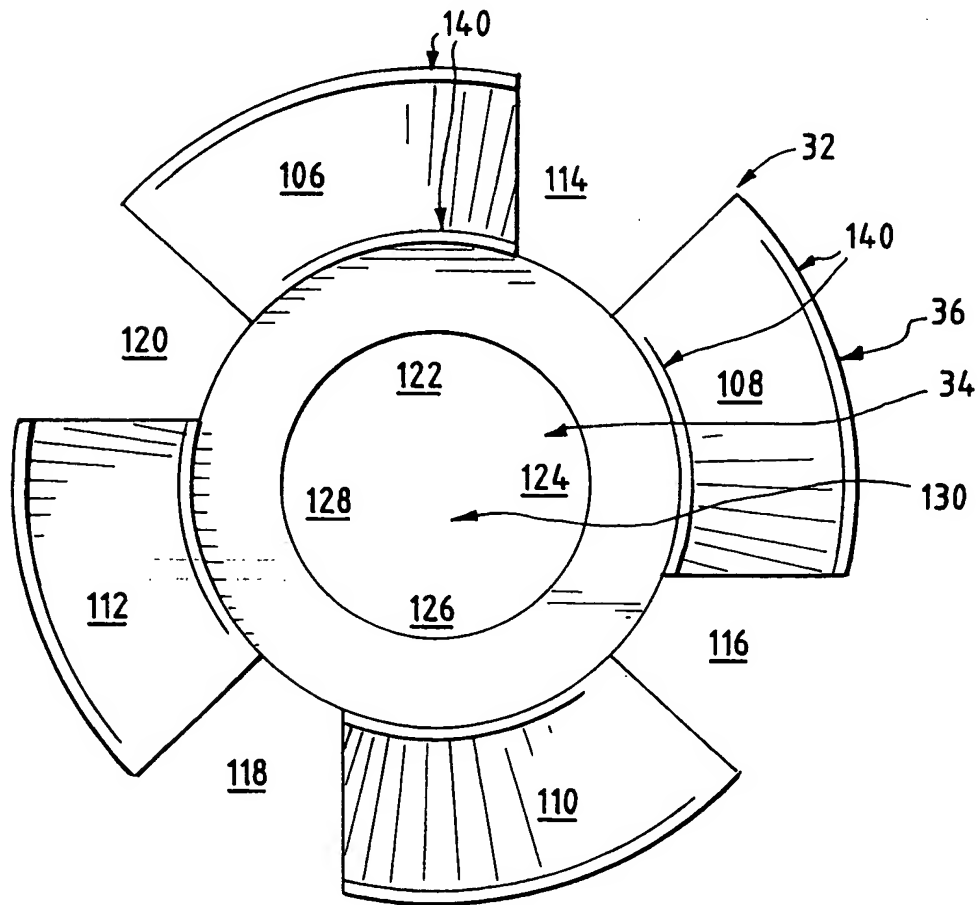
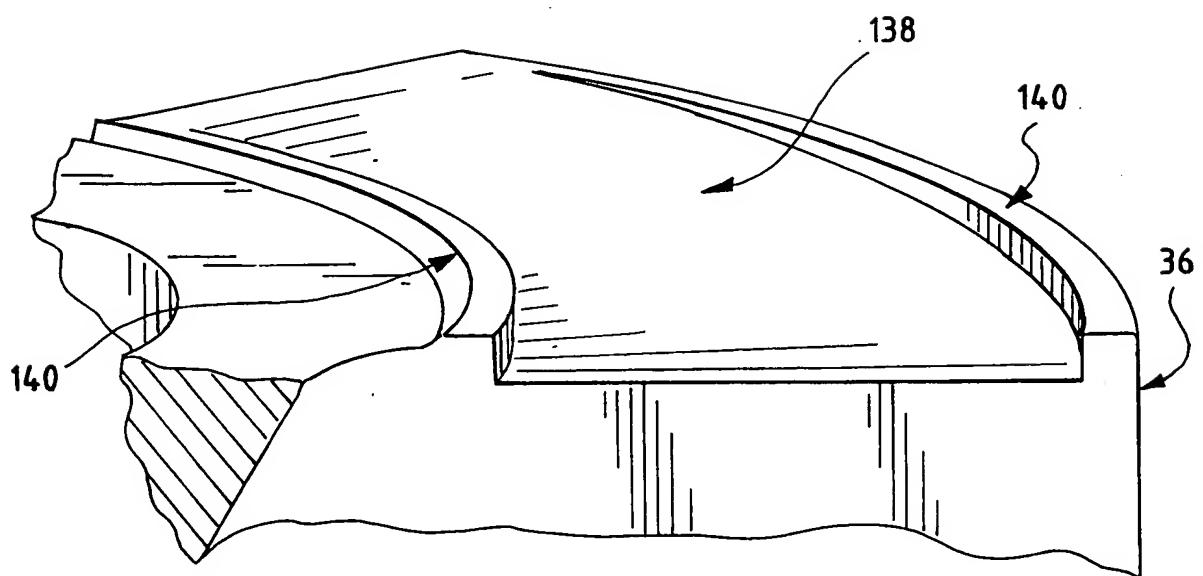


FIG. 15



TEST AVAILABLE COPY

FIG. 16



BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

Inte onal Application No

PCT/US 00/09009

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/10 F04D29/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M F04D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 840 070 A (WAMPLER) 24 November 1998 (1998-11-24) cited in the application column 2, line 13 - line 60 column 10, line 43 -column 11, line 52 figures 11-14	1,4,14
A	---	5-7, 11-13,17
X	US 5 211 546 A (ISAACSON ET AL.) 18 May 1993 (1993-05-18) column 7, line 31 - line 40 column 11, line 17 -column 12, line 68 column 17, line 30 -column 18, line 28 claim 7 figures 3,4,11-17	14
A	---	1,3,7,10
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

11 August 2000

Date of mailing of the international search report

18/08/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Schönleben, J

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

Ints. .onal Application No

PCT/US 00/09009

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 94 09274 A (THE CLEVELAND CLINIC FOUNDATION) 28 April 1994 (1994-04-28) page 7, line 7 -page 10, line 34 figure 3 ---	18,22,27
A	WO 99 12587 A (CORTRONIX PTY. LTD.) 18 March 1999 (1999-03-18) page 7, line 21 -page 12, line 12 figure 1 ---	18
A	EP 0 900 572 A (SULZER ELECTRONICS AG) 10 March 1999 (1999-03-10) column 3, line 45 -column 4, line 4 column 6, line 48 -column 7, line 7 figure 1 -----	27,31

INTERNATIONAL SEARCH REPORT

information on patent family members

Int. Application No

PCT/US 00/09009

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5840070 A	24-11-1998	US 5695471 A AU 7993698 A EP 0901797 A JP 11123239 A US 6080133 A AU 708476 B AU 2277797 A CA 2218342 A EP 0821596 A JP 11504549 T WO 9729795 A	09-12-1997 25-02-1999 17-03-1999 11-05-1999 27-06-2000 05-08-1999 02-09-1997 21-08-1997 04-02-1998 27-04-1999 21-08-1997
US 5211546 A	18-05-1993	US 5112200 A AU 8056091 A WO 9119103 A	12-05-1992 31-12-1991 12-12-1991
WO 9409274 A	28-04-1994	CA 2145857 A DE 69229964 D DE 69229964 T EP 0681654 A JP 8504490 T	28-04-1994 14-10-1999 27-01-2000 15-11-1995 14-05-1996
WO 9912587 A	18-03-1999	AU 8965498 A EP 1019116 A	29-03-1999 19-07-2000
EP 900572 A	10-03-1999	NONE	

BEST AVAILABLE COPY